

**REMARKS**

This amendment cancels claim 33 without prejudice or disclaimer, since the retained claims, which are Nos. 10, 32 and 34-61, adequately protect the invention. The examiner has withdrawn claims 10 and 37-61 from consideration. Of the claims presented for consideration on the merits, No. 32 is independent, and each of the others, namely Nos. 34-36, depends directly or indirectly on claim 32. Accordingly, if, as will become apparent from these remarks, claim 32 avoids the prior art, claims 34-36 also avoid the prior art.

When the application is in condition for allowance except for the presence of the withdrawn claims, the examiner may expedite the prosecution of this application by canceling the withdrawn claims by examiner's amendment, without prejudice to applicant's right to file one or more divisional applications directed to their subject matter.

**Drawings**

Section 2 of the Office action sets out an objection to the drawings on the ground that Fig. 3 contains expressions in the German language. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are submitted herewith. Withdrawal of the objection to the drawings is therefore respectfully requested.

**Claim Rejections – 35 U.S.C. § 101**

Section 4 of the Office action sets out a rejection of claims 32-34 (now 32 and 34) under 35 U.S.C. § 101 as being directed to non-statutory subject matter. The examiner

notes that those claims as previously presented read on the native sequence found in humans.

The rejection is respectfully traversed. Independent claim 32 has been limited to purified oligonucleotides comprising a polymorphism specified as a C10G change at position 10 of the nucleotide sequences set forth in Seq. Id. Nos. 1 and 3. Since “isolated” and “purified” are essentially synonymous, we have employed the latter term, which appears in the specification, but not both. The amended claims, while employing open claim language (“comprising”), do not read on the native sequence found in humans, and withdrawal of the rejection is respectfully requested.

#### **Claim Rejections – 35 U.S.C. § 112 – Second Paragraph**

Section 5 of the Office action sets out a rejection of claims 32-36 (now 32 and 34-36) under 35 U.S.C. § 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. The rejection is respectfully traversed for reasons given below.

1. The examiner notes that a polymorphism refers to an alteration in a sequence, and not to a sequence itself. Independent claim 32 as amended specifies a C10G change at position 10 of the nucleotide sequences set forth in Seq. Id. Nos. 1 and 3 and thus refers properly to an alteration in sequence. (The reference is first to the wild type, then to the position, and then to the change, in accordance with the conventional notation.)

2. The typographical error the examiner noted in claim 34 ("XmnT") has been corrected.

**Claim Rejections – 35 U.S.C § 112 – Written Description**

Section 7 of the Office action sets out a rejection of claims 32-36 (now 32 and 34-36) under 35 U.S.C. § 112, first paragraph, as containing subject matter which was not described in the specification in such a way as reasonably to convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. The examiner explains that the claims are broader than the disclosure. This amendment limits the claims to subject matter disclosed in the specification, including the tables, and in the drawings.

Claim 32, the only independent claim under consideration, is directed to purified oligonucleotides comprising a polymorphism characteristic for an increased or reduced risk for hypercholesterolemia in humans. The polymorphism occurs in a sterol regulator element binding protein (SREBP), the SREBP being SREBP-1. The polymorphism is located in SREBP-1-exon 18c, and is a C10G change at position 10 of the nucleotide sequences set forth in Seq. Id. Nos. 1 and 3.

The subject matter of the claims as amended is clearly disclosed in the application and is, in fact, the subject matter of the entire application. Withdrawal of the rejection is therefore respectfully requested.

**Claim Rejections – 35 U.S.C. § 112 – Scope of Enablement**

Section 8 of the Office action sets out a rejection of claims 32-36 (now 32 and 34-36) under 35 U.S.C. § 112, first paragraph, on the ground that the specification does not reasonably provide enablement for all polymorphisms in Seq. Id. No. 3. The examiner recognizes, however, in the first sentence of section 8, that the specification is “enabling for the two demonstrated polymorphisms in the SREBP gene.” Since the claims as amended are limited to enabled subject matter, withdrawal of the rejection is respectfully requested.

**Claim Rejections – 35 U.S.C. § 102**

Section 10 of the Office action sets out a rejection of claims 32-36 (now 32 and 34-36) under 35 U.S.C. § 102(a) and (b) as being anticipated by Roy et al. (Cell (1995) 80:167-178 as evidenced by Genbank Accession No. AC122129 and <http://bacpac.chori.org/clones.htm> (“Roy”). The examiner notes that Roy discloses the synthesis of BAC chromosome libraries, including the RCPI 1 or RP1 library; and that the clone RP1-253P7, derived from human chromosome 17, discloses the complete sequence of Seq. Id. No. 3. The examiner therefore concludes that Roy discloses the complete sequence of Seq. Id. No. 3 and meets the requirements of claims 32-36 (now 32 and 34-36) as previously presented.

But the amended claims are not drawn to a sequence; they are drawn instead to purified oligonucleotides comprising a specified polymorphism. In particular, as indicated

above, claim 32, the only independent claim under consideration, is directed to purified oligonucleotides comprising a polymorphism characteristic for an increased or reduced risk for hypercholesterolemia in humans. The polymorphism occurs in a sterol regulator element binding protein (SREBP), the SREBP being SREBP-1. The polymorphism is located in SREBP-1-exon 18c, and is a C10G change at position 10 of the nucleotide sequences set forth in Seq. Id. Nos. 1 and 3.

The disclosure of Roy is, of course, irrelevant to the claims as amended. Since Roy neither discloses nor suggests the invention as defined in the amended claims, the rejection under 35 U.S.C. § 102(a) and (b) should be withdrawn.

In view of the preceding amendments and remarks, favorable reconsideration of the application is respectfully requested.

Respectfully submitted,  
COOPER & DUNHAM LLP

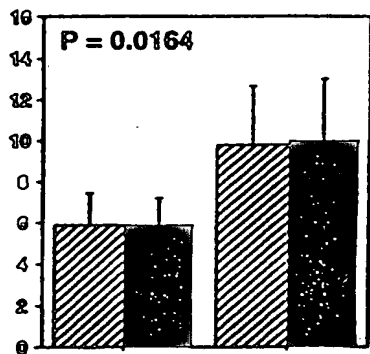


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# SREBP-1 Polymorphism (mmol/L)

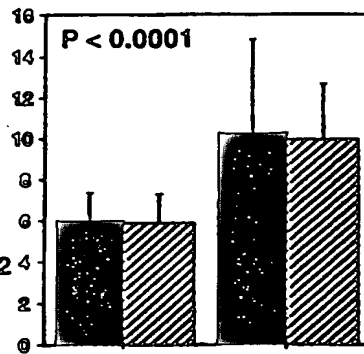
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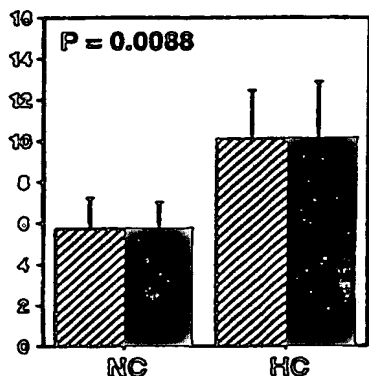
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RANDOM ← added → NOT RANDOM

# SREBP-2 Polymorphism (mmol/L)

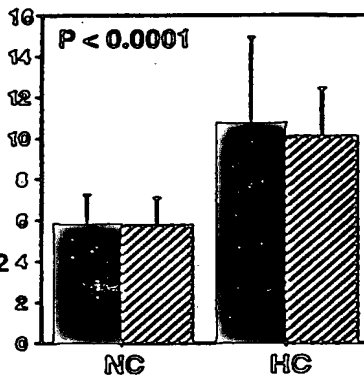
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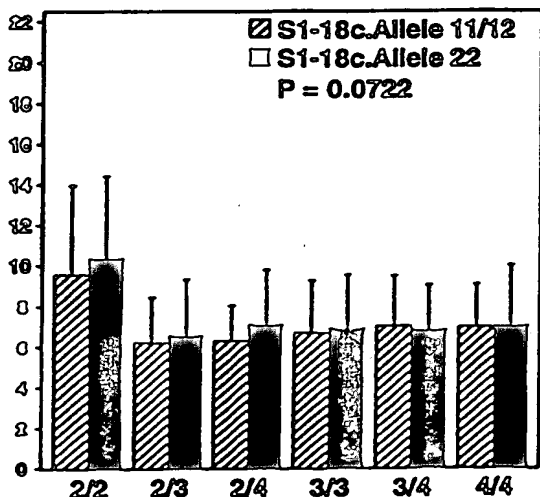
C



D



E



F

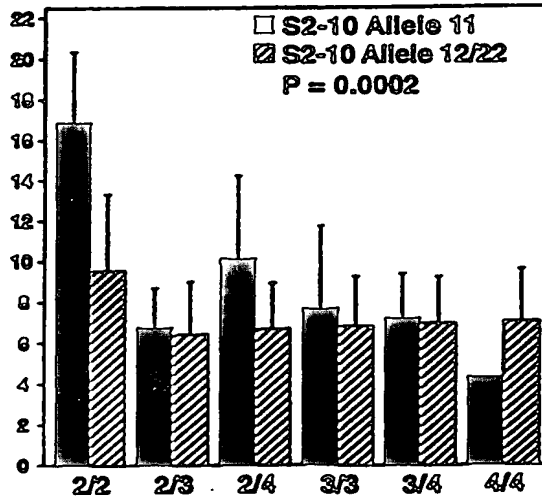


Figure 3